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David M. Stamper

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11/25/2008

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EXAMINER

DOE, SHANTA G

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

11/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/826,789

Applicant(s)

STAMPER ET AL.

Examiner

SHANTA G. DOE

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/20/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date 4/16/2004
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-9 and 12-15 in the reply filed on June 20, 2008 is acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3-6, 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 3-6 these claims are indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention because these claims as written do not further limit the invention. The claims as presented state that the applicant's invention is the improvement of having a slide holder within a known bioreactor. However, claims 3-6 do not further limit the slide holder. They further limit the bioreactor which as stated in claim 1 (based on the Jepson format of the claim) is not the applicant's invention.

Regarding claims 8 and 9, these claims are indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention because these claims as written do not further limit the invention. The

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claims as presented state that applicant's invention is the improvement of having the mid-section housing being used for the retention of the slides within the housing of a known bioreactor. However, claims 8 and 9 do not further limit the mid-section housing for retention of the slide with in the housing, they further limit the bioreactor which as stated in claim 7 (based on the Jepson format of the claim) is not the applicant's invention.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted prior art (APA) in view Wolfson (US 3,198,005).

Regarding claim 1, the applicant admits that a bioreactor having an axially elongated

housing within which biofilm growth on microscope slides and beads is effected and evaluated within the housing is prior art through the Jepson claim format. However, the admitted prior art fails to disclose the improvement which comprises a holder means for retaining at least one slide within the bioreactor housing to avoid disruption of growth of the biofilm on the beads therein, and wherein the holder means is inserted, retained and retraction, from the bioreactor in order to remove a slide therefrom.

Wolfson (US 3,198,005) discloses a bioreactor (reservoir (10 A), the test water that is fed to the reservoir is inoculated with bacterial species and media that will reproduce microbiological slime (biofilm).) comprising an inlet (12), an outlet (14) and a holder means (rectangular slide holder(26)) for retaining at least one slide(test panel 54 made of glass) within the bioreactor housing wherein the holder means is inserted, retained and retracted from the bioreactor in order to remove a slide therefrom(see fig 1,2 4 and 5, col. 2 lines 46 -62, col.3 lines 30-45, col. 4 lines 35-43 and col. 5 lines 50-54).

In view of Wolfson, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the known bioreactor further include a slide holder (holder means for retaining at least one slide) as taught by Wolfson because such a modification would enable one to remove multiple slides from the bioreactor for inspection, examination and testing of the biofilm growth on the slides.

Regarding claim 3, the combined references as applied to the combination as defined in claim 1, further includes a port means (the upper/top part of the reservoir (10) has an

opening/port through which the biofilm on the slide holder could be evaluated without disruption of the biofilm) on the bioreactor for evaluation of the biofilm without disruption of the biofilm. The combined reference fails to disclose that the port is connected to the bioreactor. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the port means be connected to the bioreactor since the port means being connected to the bioreactor does not functionally distinguish it from the port as taught by the combined references (whether the port means is part of the reactor or connected to the reactor, both port means can be used as a means of evaluation of the biofilm without disruption)

6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted prior art (APA) in view Wolfson (US 3,198,005) as applied to claim 1 above, and further in view of Peyton et al. (US 5,641,642).

Regarding claim 2, the combined references (APA and Wolfson) disclose the combination as defined in claim 1. However; the combined references fail to disclose that the bioreactor and holder means combination of claim 2 further including actuating means for extending into the holder means for retraction of the holder means from the bioreactor.

Peyton (US 5,641,642) discloses a bioreactor comprising a holder means (sampling coupon (10) holds packing material for the accumulation of biofilm thereon and removal of the biofilm from the bioreactor for analyzing) wherein there is an actuating means (cable (56) affixed to an attachment means 58 on the sampling coupon 10 for inserting and removing the coupon from the bioreactor) (see col. 2 line 50-col. 3 line 20).

In view of Peyton, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the combined reference further comprise actuating means for extending into the holder means for retraction of the holder means from the bioreactor as taught as Peyton in order to facilitate easy removal and insertion of the holder means into/out of the bioreactor.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted prior art (APA) in view of Wolfson (US 3,198,005) as applied to claim 1 above, and further in view of Familletti (US 5,081,036).

Regarding claim 4, the combined references as applied to claim 1 above disclose the combination as defined in claim 1. The combined references fail to specifically disclose that the bioreactor includes an inlet means connected to a test chamber of the housing for aeration, an inlet means connected to a test chamber of the housing for feed of nutrients and an outlet means.

Familletti (US 5,081,036) discloses that it is known in the art for bioreactors to comprise an inlet means connected to a test chamber of the housing for aeration, an inlet means connected to a test chamber of the housing for infeed of nutrients and an outlet means wherein the inlets serve as means for introducing feed medium and air in to the reaction chamber and the outlet serves as a means of withdrawing the reaction product or spent media from the reactor chamber.

In view of Familletti, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the bioreactor of the combined references comprise inlet means connected to a test chamber of the housing for aeration, an inlet means connected to a test chamber of the housing for infeed of nutrients and an outlet means since it was well known in the art as taught by Familletti that the inlets serve as means for introducing feed medium and air in to the reaction chamber and the outlet serves as a means of withdrawing the reaction product/ or spent media from the reactor chamber.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted prior art (APA) in view of Wolfson (US 3,198,005) as applied to claim 1 above, and further in view of Gaugler et al (US 6,432,698).

Regarding claim 5, the combined references as applied to claim 1 above disclose the combination as defined in claim 1. The combined references fail to specifically disclose

that the axially elongated housing of the bioreactor has a length to width ratio of a magnitude to aerate the slides and beads, wherein the ratio is from 10:1 to about 5:1.

Gaugler et al (US 6,432,698), disclose a bioreactor wherein the bioreactor housing/container being longer than wider is preferred and in some embodiment the length to width ratio of the housing is between about 2:1 and 5:1 (see col. 4 lines 31 -35, col.7 lines 3-5, claim 2 and 3).

In view of Gaugler, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the axially elongated housing of the bioreactor of the combined references have a length to width ratio wherein the ratio is from 10:1 to about 5:1 since Gaugler states at col.4 lines 31-35 that elongating the bioreactor housing is beneficial if a greater gas exchange is desired.

Furthermore, in view of Gaugler disclosure, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the axially elongated housing of the bioreactor have a length to width ratio of 10:1 to about 5:1, since it has been held that where the general conditions (the desire to elongate (the housing being longer than is wider) the bioreactor housing in order to achieve a greater gas exchange within the reactor) of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted prior art (APA) in view of Wolfson (US 3,198,005) as applied to claim 1 above, and further in view of Rigg et al (US 5,910,434) and Roth (US 5,833,857) .

Regarding claim 6, the combined references as applied to claim 1 above disclose the combination as defined in claim 1. The combined references fail to specifically disclose that the surface area to volume is obtained between surface area of a housing chamber in the bioreactor, on the slides and on the beads, and volume of a quantity of liquid in the housing chamber; and wherein said surface area to volume is at least 10 square cm per 1 ml.

Roth discloses that it is desired in the art to have a high surface area to volume ratio because this allows for a smaller reactor size while maintaining a faster throughput (col. 2 lines 37 -39)

Riggs discloses that it is known in the art for a packed-bed bioreactor to have a surface area to volume ratio of about 5 to 50 cm square/ml (see Rigg col. 17 lines 45 - 48).

In view of Roth and Rigg, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the surface area to volume be at least 10 square cm per 1 ml since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum value involves only routine skill in the art.

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art.

Regarding claim 7, the applicant admits that a bioreactor having an axially elongated housing within which biofilm growth on microscope slides and beads is effected and evaluated within the housing is prior art through the Jepson claim format. However, the admitted prior art fails to specifically disclose the improvement which discloses that the/a mid- housing section is for retention of the slides within the housing to enhance said growth of the biofilm thereon.

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the mid-section of the elongated housing of the bioreactor be used for the retention of the slides since it has been held that rearranging parts of an invention involves only routine skill in the art. Furthermore, the mid-housing section of the bioreactor being used for the retention of slides is an intended use of the mid-housing section and this limitation does not further limit the claim invention

11. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art as applied to claim 7 above, and further in view of Familletti (US 5,081,036) .

Regarding claim 8, the reference as applied to claim 7 above disclose the combination as defined in claim 7. The reference fails to specifically disclose the bioreactor further including an inlet port for aeration flow, an inlet port for liquid and an outlet port.

Familletti (US 5,081,036) discloses that it is known in the art for bioreactors to comprise an inlet means connected to a test chamber of the housing for aeration, an inlet means connected to a test chamber of the housing for infeed of liquid nutrients and an outlet means wherein the inlet serves as means for introducing feed medium and air in to the reaction chamber and the outlet serves as a means of withdrawing the reaction product or spent media from the reactor chamber (see fig 1).

In view of Familletti, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the bioreactor of the combined references comprise inlet means connected to a test chamber of the housing for aeration, an inlet means connected to a test chamber of the housing for infeed of nutrients and an outlet means since it was well known in the art as taught by Familletti that the inlet serves as means for introducing feed medium and air in to the reaction chamber and the outlet serves as a means of withdrawing the reaction product or spent media from the reactor chamber.

Regarding claim 9, the combination as defined in claim 8, further includes an inlet port(called an outlet) for withdrawing a fluid sample for evaluation.

12. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art in view of Wolfson (US 3,198,005) and Gaugler et al (US 6,432,698) .

Regarding claim 12, the applicant admits that a bioreactor having an axially elongated housing within which biofilm growth on microscope slides and beads is effected and evaluated within the housing is prior art through the Jepson claim format of claim 1. However, the admitted prior art fails to disclose that the axially elongated housing has a length to width ratio of about 10:1 to about 5:1 and a rectangular holder removeably positioned within the elongated housing for retaining of said slides.

Wolfson (US 3,198,005) discloses a bioreactor (reservoir (10 A), the test water that is fed to the reservoir is inoculated with bacterial species and media that will reproduce microbiological slime (biofilm).) comprising an inlet (12), an outlet (14) and a holder means (rectangular slide holder(26)) for retaining at least one slide(test panel 54 made of glass) within the bioreactor housing wherein the holder means is inserted, retained and retracted from the bioreactor in order to remove a slide therefrom(see fig 1,2 4 and 5, col. 2 lines 46 -62, col.3 lines 30-45, col. 4 lines 35-43 and col. 5 lines 50-54).

In view of Wolfson, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the known bioreactor further include a slide holder (holder means for retaining at least one slide) as taught by Wolfson because such a modification would enable one to easily remove multiple slides from the bioreactor for inspection, examination and testing of the biofilm growth on the slides.

The combined references (APA and Wolfson) above fail to disclose that the axially elongated housing has a length to width ratio of about 10:1 to about 5:1.

Gaugler et al (US 6,432,698), disclose a bioreactor wherein the bioreactor housing/ container being longer than wider is preferred and in some embodiment the length to width ratio of the housing is between about 2:1 and 5:1 (see col. 4 lines 31 -35, col.7 lines 3-5, claim 2 and 3).

In view of Gaugler, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the axially elongated housing of the bioreactor of the combined references have a length to width ratio wherein the ratio is from 10:1 to about 5:1 since Gaugler states at col.4 lines 31-35 that elongating the bioreactor housing is beneficial if a greater gas exchange is desired.

Furthermore, in view of Gaugler disclosure, it would have been obvious to one having ordinary skill in the art at the time the invention was made to the axially elongated housing of the bioreactor has a length to width ratio of 10:1 to about 5:1, since it has been held that where the general conditions (the desire to elongate (the housing being longer than is wider) the bioreactor housing in order to achieve a greater gas exchange within the reactor) of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

13. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art (APA) in view of Wolfson (US 3,198,005) and Gaugler et al (US 6,432,698) as applied to claim 12 above, and further in view of Peyton (US 5,641,642) .

Regarding claim 13, the combined references as applied to claim 12 above disclose the

bioreactor arrangement of claim 12 comprising a sealable top end portion at an upper end (see Wolfson fig 1&4) of the axially elongated housing. However, the combined references fail to disclose that the device of claim 12 further comprises at least one actuator within the elongated housing, protruding above the sealable top end portion and extending through the rectangular holder.

Peyton (US 5,641,642) discloses a bioreactor comprising a holder means (sampling coupon (10) holds packing material for the accumulation of biofilm thereon and removal of the biofilm from the bioreactor for analyzing) wherein an actuating means (cable (56) is affixed to an attachment means 58 on the sampling coupon 10 for inserting and removing the coupon from the bioreactor housing, the cable extends in to the open end of the bioreactor) (see col. 2 line 50-col. 3 line 20).

In view of Peyton, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the combined reference further comprise at least one actuator within the elongated housing, protruding above the sealable top end portion and extending through the rectangular holder as taught as Peyton in order to facilitate easy removal and insertion of the holder means into/out of the bioreactor.

14. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art (APA), Wolfson (US 3,198,005), Gaugler et al (US 6,432,698) and Peyton (US 5,641,642) as applied to claim 13 above, and further in view of Trevarrow (US 4,561,815).

Regarding claim 14, the combined references as applied to claim 13 above disclose the bioreactor arrangement of claim 13, wherein the rectangular holder comprises a bottom portion with a threaded opening (see fig 5). However the references fail to disclose that the at least one actuator comprises a rod having a threaded end, wherein the threaded end of the rod is threadedly inserted into the threaded opening in the bottom portion of the rectangular holder.

Trevarrow (US 4,561,815) discloses that actuator comprises a rod having a threaded end, wherein the threaded end of the rod is threadedly inserted into the threaded opening in a holder is known in the art.

In view of Trevarrow, it would have been obvious to one having ordinary skill in the art at the time of the invention to replace the actuator and holder arrangement of the combined reference with an actuator comprises a rod having a threaded end, wherein the threaded end of the rod is threadedly inserted into the threaded opening in the holder as taught by Trevarrow, since the substitution of one known actuator and holder assembly for another would have yielded a predictable result of using the actuation means to move the holder from one position to another.

15. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art (APA), Wolfson (US 3,198,005), Gaugler et al (US 6,432,698) and Peyton (US 5,641,642) and Trevarrow (US 4,561,815) as applied to claim 14 above, and further in view of Familletti (US 5,081,036).

Regarding claim 15, the references as applied to claim 14 above disclose the bioreactor arrangement of claim 14. However, the references fail to disclose that the device of claim 14 further comprises: an aeration inlet port; a feed supply inlet port; a testing inlet port; and an outlet port.

Familletti (US 5,081,036) discloses that it is known in the art for bioreactors to have multiple ports located on the device for various reasons such as an inlet port connected to a test chamber of the housing for aeration, an inlet port connected to a test chamber of the housing for infeed of liquid nutrients and an outlet.

In view of Familletti, it would have been obvious to one having ordinary skill in the art to have the bioreactor of the combined references comprise multiple ports since it was well known in the art as taught by Familletti that these ports serve as a means to introduce and withdraw substances from the bioreactor.

The above combined references above do not specifically disclose that the device comprises multiple ports wherein the number of ports is four. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the multiple ports on the device be four, since it has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANTA G. DOE whose telephone number is (571)270-3152. The examiner can normally be reached on Mon-Fri 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GSD

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797